In the Drawings

Please Amend the Drawings of the above Referenced Application as Follows:

Please add new Figure 32 as shown in the attached sheet of drawings labeled as "New Sheet."

REMARKS

I. Overview/Interview Summary

The Applicants and their attorney would like to thank Examiners Ali and Mitchell for the courtesies that they extended to the Applicants, Denis Irlbeck and Kevin Burrow, and Applicants' attorney E. Victor Indiano, at the interview that was held on 7 September 2005.

In the interview, the Applicants demonstrated a breathing circuit to the Examiners that was made according to the teachings of the present application. The Applicants also discussed the history of the development of the breathing circuit, and the significant problems and obstacles that the Applicants encountered in developing the instant invention.

The Applicants also discussed the technical objections that Examiner Mitchell had to the drawings, and to the specification, and pointed out those changes, set forth in the proposed Amendment that was earlier forwarded to Examiner Mitchell. It was the Applicants' Attorney's impression that, for the most part, the proposed changes suggested by the Applicant overcame the Examiner's objections to the specification. Additionally, the Applicants promised the Examiner that they would provide a new drawing (Fig. 32) that overcame the objections raised by the Examiner to the drawings in the Official Action.

The Applicants, Mr. Indiano and the Examiners then discussed the prior art, and the differences between the Applicants' invention and the Clawson and Nowacki references cited by the Examiner. In her Interview Summary form, Examiner Mitchell sets forth fairly the substance of the topics discussed.

In this Amendment, the Applicants seek to address the comments and issues raised by the Examiner during the interview, and to address the rejection of the claims made under Sections 102 and 103. Additionally, the Applicants in this response, have endeavored to show support in the specification for the limitations raised in the claims.

II. Objections to the Drawings

The Examiner objected to the drawings, believing that they did not disclose every feature of the invention specified in the claims. In particular, the Examiner believed that the Applicants need to show, in the drawings, an illustration of the length of the inspiratory tube being greater than the length of the expiratory tube.

With this Response, the Applicants have submitted a new drawing denominated as Figure 32, that shows an inspiratory tube and an expiratory tube next to each other, with the inspiratory tube being shown as having a length, when in its fully expanded position, that is greater than the length of the expiratory tube when the expiratory tube is in its fully expanded position.

The Applicants submit that this drawing does not introduce new matter, as it is fully supported by the specifications and, the claims, that form a part of the disclosure. In particular, the Examiner's attention is directed to Claims 1-3 that disclose that the inspiratory tube is longer than the expiratory tube, and also to paragraphs 86 and 99-100 of the Specification wherein the greater length of the inspiratory tube, when compared to the expiratory tube, is discussed in more detail.

III. Objections to the Specification

The Examiner next objected to the disclosure because of informalities that were contained at paragraphs 82, 86 and 87. With this Amendment, the Applicants have amended paragraphs 82, 83, 84, 86 and 87 to overcome these inconsistencies discussed by the Examiner. It is believed that these amendments overcome the Examiner's objections to the claims.

Additionally, the Applicants have amended other portions of the claims, to correct errors, and to clarify the Specification.

The Examiner's attention is first directed to the changes made to paragraphs 28, 32 and 36. In these paragraphs, the term "corrugated" has been changed to the term "pleated". As will be discussed below, similar changes were made to the claims of the application.

The Applicants would like to first point out that the term "pleated" is supported in the Specification. In particular, the Examiner's attention is directed to paragraph 142, that states:

> "The expiratory tube 508 and inspiratory tube 510 are constructed generally similarly to the expiratory tube 26 and inspiratory tube 22 shown in Fig. 1. Both 508, 510 comprise accordion-type tubes containing a plurality of pleats, wherein each pleat is movable between an expanded

position...and a compressed position... ."

The Applicant has chosen to substitute the term "pleat" for the term "corrugated", as the Applicants believe that the term "pleat" more accurately describes the nature of the Applicants' tube than does the term "corrugated". The term "pleat" better conveys the nature of a tube having undulations joined at a fold line, as described in great detail in the Specification. By contrast, the term "corrugated", while describing the tube as being one that has undulations, does not convey the notion of the undulations being joined at a fold line.

An additional change to the Specification was made at paragraph 72, 73 and 99. The changes in these paragraphs were made to incorporate the new drawing, Fig. 32, within the Specification. As discussed above, the addition of the material shown in Fig. 32 is clearly supported by the Specification, and does not add new matter.

Finally, the Applicants have amended the specification at paragraph 122 to correct an obvious transcription error. The fact that an occurrence of "inspiratory tube 22" should be changed to "expiratory tube 26" is born out of the following sentence that talks about the differences in angles being due to differences in size between the inspiratory tube and expiratory tube. Additionally, the Examiners' attention is directed to paragraph 117-120 that describes in some detail, the differences in angles between the inspiratory tube and expiratory tube.

IV. The Applicants' Invention and the Art of Record

A. Introduction

As discussed with the Examiners at the interview, the Clawson and Weigl reference does disclose the broad concept creating a co-axial respiratory circuit having a corrugated outer circuit, and a corrugated inner circuit, wherein the corrugations are compressible and expandable between a compressed state and an extended state, so that the user can vary the length of the corrugated breathing circuit.

Notwithstanding Clawson's broad disclosure of the use of a unilimb circuit having an inner and outer "pleated" tube, Clawson discloses little about how to construct such a co-axial respiratory circuit containing pleated tubes, that will be safe and efficacious in a real world environment.

As also discussed at the interview, the creation of a safe and efficacious breathing circuit comprised of inner and outer variable rest length tubes requires much more than just the placement of a variable rest length inner tube, within a variable rest length outer tube.

B. Claims 1-3

The Examiner rejected Claim 1 under Section 102 as being anticipated by Clawson and Weigl, PCT Publication No. WO 85/05277.

One hurdle that must be overcome to create a safe and efficacious breathing tube is to design a tube that is resistant to becoming disconnected from its connection with the end connector. In particular, it is important that the proximal (machine) end of the inner tube not become disconnected from its connection to its proximal end connector. In order to prevent such disconnects, the Applicants found that it was important that the inspiratory tube be formed to have a length greater than the expiratory tube, when each were in their fully expanded position. By so doing, the full expansion of the expiratory tube does not place undue stress on the connection between the proximal end of the inspiratory tube and the proximal end connector. By avoiding such stress, the risk of a disconnect is decreased.

The Applicants' Claim 1 recites such a limitation. However, this concept of making the inspiratory tubes longer than the expiratory tube to avoid disconnects was clearly not appreciated by Clawson. At page 14, Clawson states the following:

> "Conduits or tubes 108 and 110 are formed with special convolutions. *There is no need to match them or cut them to matching lengths.* They can be assembled with the manifold easily by extending the corrugations of the inner conduit in compressing those of the outer conduit while connecting the ends of the inner one to nozzle 100 in fitting 118... "(Emphasis added).

From this paragraph, it is clear that Clawson has no appreciation of the problem solved by Applicants' invention which, in Applicants' Claim 1, recites that the lengths of the inspiratory tube is greater than the length of the expiratory tube.

Nor does Clawson, anywhere in his very abbreviated discussion of Fig. 4 disclose or suggest the amount by which the inspiratory tube should have a length greater than the length of the expiratory tube, as further defined in Claims 2 and 3.

C. Claim 4

The Examiner rejected Claim 4 as being obvious over Clawson, in view of Nowacki, U.S. Patent No. 4,621,634.

Nowacki's '634 patent discloses a Bain circuit. It is first important to note that a Bain circuit is not a rebreathing circuit. In a rebreathing circuit (such as the Applicants'), exhaled gas is directed back to an anesthesia machine, wherein it is mixed with fresh gas, oxygen, and stripped of its carbon dioxide, and recirculated back to the patient. By contrast, a non-rebreathing, Bain circuit does not recirculate the patient's expired gas. Because the gas is not recirculated, the inspiratory tube is almost always smaller, and feeds gas, under pressure, to the patient. Because of the smaller inspiratory tube used with a non-rebreathing circuit, a small diameter inspiratory tube, of the type shown by Nowacki, will not cause as much resistance to flow in the expiratory conduit as is typically encountered with the larger inner tube of a rebreathing circuit.

Claim 4 includes a recitation that "the distal and coupling member includes an axis-containing terminus for receiving the inspiratory tube, [with] the axis of the terminus being radially offset from the axis of the distal end coupling member.

The benefit obtained by the Applicants' offset terminus is to reduce flow resistence in the expiratory pathway at the patient end of the circuit.

The reduction of flow resistance does not appear to have been a motivating factor for Nowacki's offset tube. Rather, it appears that Nowacki's primary motivator for making his inner tube offset at the patient end was either to provide a crank effect that facilitates assembly of the tapered exhaust fitting, to thereby ensure a tighter connection (as recited at col. 1, ll 55-58) or to provide an inexpensive and secure anesthesiology tubing connection, that are made more secure than those in the prior art, due to the interlocking construction. See, col. 4, ll 66-69 and col. 5, ll1-2 of Nowacki, U.S. Patent No. 4,621,634.

Nowhere in Nowacki is there any disclosure or suggestion of using a radially offset

connector for the purpose of reducing flow resistence. Most likely, there is no disclosure or suggestion in Nowacki of using the radial offset to decrease flow resistance, due to the fact that flow resistence is not a major issue when using the relatively smaller diameter inspiratory tubes typically used in non-rebreathing type Bain circuits.

Nor is it necessarily apparent that flow resistance will be unduly compromised by the use of a non-offset inner tube in a rebreathing circuit of the prior art. In this regard, the Examiner's attention is directed to Leagre et al., U.S. Patent No. 5,404,873 and Fukunaga et al., U.S. Patent No. 5,778, 872, and its progeny.

The Assignee of the instant application manufactures the devices that are disclosed in the Leagre and Fukunaga patents. Both patents disclose the use of coaxial circuits, wherein the inspiratory tube is centered at the patient end within the expiratory tube, so that both the inspiratory and expiratory tubes share (within tolerances), a common axis at the patient end. Both of the devices perform admirably, with no significant problems related to flow resistance.

Based on this experience, there would have been no reason for the Applicants' to anticipate that the use of a pleated tubing (as opposed to the non-pleated, corrugated tubing used in the Leagre and Fukunaga devices) would have created any flow resistance problem at the patient end. However, the use of pleated circuits did create flow resistance problems at the patient's end, that the Applicants addressed by creating the inventive radially offset design that is disclosed and claimed in the Applicants' Claim 4.

As such, as neither Clawson nor Weigl, either singly or combined, disclose or suggest using the radially offset distal terminus for the inspiratory tube in a rebreathing circuit, the Applicants submit that their Claim 4 patentably distinguishes their invention over the art of record.

D. Claims 5-11

The Examiner rejected Claim 5 as being either anticipated or rendered obvious by Clawson.

The Applicants' Claim 5 includes a recitation that "the ratio of the outer diameter of the inspiratory tube to the inner diameter of the expiratory tube is sized to minimize flow resistance therebetween, while facilitating generally linear compressibility and expandability

of the inspiratory and expiratory tubes".

The Applicants submit that this is not disclosed or suggested by Clawson.

Clawson states very little, if anything, about the relative size of the inspiratory tube and expiratory tube. It appears that Clawson did not believe that the relative sizing of the tube was important, for he states that "there is no need to match [the inspiratory and expiratory tubes]... or cut them to matching lengths. (See Clawson at p. 14).

From the drawing in Clawson, it appears that the ratio of the outer diameter of the inspiratory tube 108 to the inner diameter of the expiratory tube 110, is probably less than .50 that is below the ranges set forth in Applicants' Claims 7 through 10.

As discussed in more detail in the Specification, it is important to match the sizes of the inspiratory tube to the expiratory tube to achieve a proper balance, such that both flow resistence is minimized in the expiratory passageway, and that linear compressibility and expandability of the inspiratory and expiratory tubes is facilitated. If for example, the inspiratory tube is much smaller than the expiratory tube (such as is shown in Clawson's Fig. 4), compressibility and expanability will be compromised, because the compression of the expiratory tube will likely cause the inspiratory tube to "snake" within the expiratory tube, to thereby possibly increase the flow resistance. Alternately, if the inspiratory tube is too large relative to the expiratory tube, it is likely that flow resistance will be increased to an unacceptable level when the circuit is compressed, due to the fact that the outer diameter of the inspiratory tube is greater when the tube is compressed when compared to when the tube is expanded, which thereby reduces the cross-sectional area of the expiratory pasasgeway.

As Clawson does not appear to appreciate the problem discovered by Applicants, Clawson can not be said to disclose or suggest the Applicant's solutions of providing tubes wherein the ratio of the outer diameter of the inspiratory tube to the inner diameter of the expiratory tube are sized to minimize flow resistance therebetween, while facilitating generally linear compressability and expandability of the tubes, as recited in the Applicants' Claim 5. Nor, does Clawson disclose or suggest any of the ratios disclosed in Claims 7 - 10, or disclose that his circuit is capable of receiving the flow resistance levels claimed in Claim 6.

E. New Claims 12-19

The Applicants have also added a new Claim 12, and Claims 13-19 which depend therefrom. Claim 12 was added to protect another feature of Applicant's invention that is disclosed in the Specification, and that was discussed during the interview. During the interview, it was discussed with the Examiner that one of the hurdles that the Applicants needed to overcome, in order to create a safe and efficacious breathing circuit having inner and outer pleated tubes, was to design an array of pleats, that permitted the inner and outer tubes would be generally expandable over the same length. Or in other words, to design pleats that would permit the relatively smaller diameter inspiratory tube to be stretched as far as the relatively larger diameter of the expiratory tube.

As explained in the extensive discussion of the mold blocks, from which the tube is made, and in particular at paragraphs 118-122 of the Specification, the Applicants were able to achieve this expandability by allowing the first and second legs of each pleat of the inspiratory tube be spread apart by a greater angle, when in the fully expanded position than the angle at which the first and second legs of the expiratory tube are allowed to be spread apart, when the expiratory tube is in its fully expanded position. Claim 12 includes recitations to this effect.

This recited feature was neither disclosed nor suggested in Clawson or Nowacki, who, as stated above, appear to have seen no reason to worry about matching the inspiratory and expiratory tubes to each other.

V. Conclusion

For the reasons set forth above, the Applicants submit that their claims, as amended, patentability distinguish their invention from the art of record. Re-examination and re-consideration of the claims, culminating in the allowance thereof, is respectfully requested.

Applicant requests that this Response be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicant requests that any required fees needed beyond those submitted with this Response be charged to the account of **E. Victor Indiano, Deposit Account Number 50-1590.**

Respectfully submitted,

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